UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/582,266 | 06/09/2006 | Michael Chorny | RCHP-101US | 1341 |

23122 7590 02/18/2009
RATNERPRESTIA
P.O. BOX 980
VALLEY FORGE, PA 19482

| EXAMINER | |
|---|---|
| DESAI, ANAND U | |
| ART UNIT | PAPER NUMBER |
| 1656 | |
| MAIL DATE | DELIVERY MODE |
| 02/18/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/582,266 | CHORNY ET AL. | |
| | Examiner | Art Unit | |
| | ANAND U. DESAI | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,8-17,19-36,49,50 and 52-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17,19-36,49,50 and 52-62* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20081114*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2008 has been entered.

2. Claims 7, 18, 37-48, and 51 are cancelled.

3. Claims 1-6, 8-17, 19-36, 49, 50, and 52-62 are currently pending and under examination.

4. All rejections not recited below are hereby withdrawn.

### *Information Disclosure Statement*

5. The information disclosure statement (IDS) submitted on November 14, 2008 is being considered by the examiner. A signed 1449 form is attached with the instant office action.

### Withdrawn Rejections

6. The rejection of claims 1-17, 19-36, and 48-50 under 35 U.S.C. 102(b) as being anticipated by Schacht et al. (U.S. Patent 6,458,386 B1; previously cited) is withdrawn based on the amendment to the claims to recite a size limitation.

***Claim Objections***

7. Claim 14 is objected to because of the following informalities: the status identifier should be currently amended. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 11/14/2008 has introduced NEW MATTER into the claims. Newly added claims 55 and 56 recites that the bioactive agent and the complexing agent are conjugated. The remark response cites page 13, lines 15-33 for support for newly added claims 55 and 56. The section cited does not disclose a conjugated bioactive agent with a complexing agent, rather discusses a non-covalent association. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02

and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claims 55 and 56 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in newly added claims 55 and 56 which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present claims 55 and 56 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-6, 8, 13, 22-26, 52, 57, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by DeFelippis et al. (U.S. Patent 7,144,863 B2).

DeFelippis et al. disclose a composition comprising GLP-1 complexed with a basic polypeptide (see Abstract). DeFelippis et al. disclose the mean diameter of the particle is between 3 microns to 5 microns in size, with 90% of the particles in the composition being less than 12 microns (see col. 4, lines 50-54). The complexed basic polypeptide is selected from the group consisting of polyarginine, protamine, and polylysine (see claims 1 and 2).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-6, 8-17, 19-36, 49, 50, 52-54, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeFelippis et al. (U.S. Patent 7,144,863 B2) in view of Gref et al. (U.S. Patent 5,543,158) and Schacht et al. (U.S. Patent 6,458,386 B1; previously cited).

DeFelippis et al. disclose a composition comprising GLP-1 complexed with a basic polypeptide (see Abstract). DeFelippis et al. disclose the mean diameter of the particle is between 3 microns to 5 microns in size, with 90% of the particles in the composition being less than 12 microns (see col. 4, lines 50-54). The complexed basic polypeptide is selected from the group consisting of polyarginine, protamine, and polylysine (see claims 1 and 2).

Gref et al. disclose methods of making nanoparticles ranging in size from 1 nm to 1000 microns using art recognized techniques (see for example col. 3, lines 55 to 64, and col. 14, lines 25 through col. 15, lines 38, and claims 4-6).

Schacht does disclose the wound dressing fabrication in the form of microparticles. The wound dressing can contain PDGF, and dextran sulfate (see e.g., col. 6, lines 42-col. 7, line 16). The composition, wherein the biopolymer matrix further comprises one or a mixture of two or more of the following compounds: a polysulfated oligo- or polysaccharide or fragments thereof; a biocompatible polyanion which has the capacity to bind heparin-binding growth factors; a proteoglycan containing glycosaminoglycan chains capable of binding to heparin-binding growth factors; a functional analogue of heparin which binds or stabilizes heparin-binding growth

factors; a monoclonal or polyclonal antibody or a microprotein wherein said antibody or microprotein has a high and selective affinity for molecular factors that can modulate the wound healing process, and wherein said microprotein can be obtained by phage display; a therapeutically effective amount of a drug; compounds having substantial affinity for the incorporated drug, so as to slow down the release of the drug from the matrix and/or stabilizing the drug. Schacht et al. disclose a controlled or slow release device comprising microparticles of a composition loaded with a drug, which can be injected intravenously, subcutaneously, or intramuscularly. The composition, wherein the polysulfated oligo- or polysaccharide is selected from one or more of the following: heparin, heparin sulfate, chondroitin sulfate, dermatan sulfate, and dextran sulfate. The composition, wherein the drug is selected from the group consisting of an EGF, a FGF, a TGF-.beta., an IGF, a PDGF, and keratinocyte cell lysate (see claims 1, 2, 12, and 19). Furthermore, the word, "join" can be reasonably interpreted to mean an association. Schacht et al. does disclose a composition with the association of a polysaccharide, dextran, with a growth factor, PDGF, in a gelatin polymer matrix (see claims 2, 12, and 19).

It would have been obvious to the person having ordinary skill in the art to manufacture a particle comprising a complex comprising a bioactive agent joined to a complexing agent, and wherein the particle diameter is from about 1 nm to about 1000 microns, because it was well known in the art how to manufacture such size particles with biologically active agents, including peptides as disclosed by the teachings of Gref et al. It would have been obvious to the person having ordinary skill in the art to complex the bioactive agent, because it was known in the art that complexing can affect the release rate of bioactive agents as disclosed by Schacht et al.

Therefore all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

***Conclusion***

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 17, 2009

/ANAND U DESAI/
Primary Examiner, Art Unit 1656